K090793

510(k) SUMMARY

MAY 19 2009

Submitter:

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US Agent:

Name: Alex Chang

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Official Correspondent:

Name: Hyun-Seung Ryu, Ph.D

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Device Identification

Proprietary Name: Bongros®-HA

Common/Usual Name: Bone grafting material

Classification Name: Bone Grafting Material, Synthetic , 872.3930

Product Code: LYC

Review Panel: Dental

Substantially Equivalent Predicate Legally Marketed Devices

The subject device is deemed to be substantially equivalent to those following devices manufactured and currently available in commercial distribution.

Device Name	**Osteograf**	**EndoBon**	**SynOss**	**Bio-Oss**
510(k) Number	K981182	K980679	K072397	K952619
Decision	SE	SE	SE	SE
Product Code	LYC	LYC	LYC	LYC

Device Description

Bongros®-HA is made of highly pure, synthetic hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$). Bongros®-HA has trabecular structure that resembles the 3-dimensional interconnected pore structure of human cancellous bone. When Bongros®-HA is placed in direct contact with viable bone, the reticulated spaces in the implant are infiltrated with hard tissue. Bone formation occurs in apposition to the Bongros®-HA surface and within the interstices of the implant skeleton.

Bongros®-HA have three specific models which are HAGS, HAGM and HAGL. The quality of the material of HAGS, HAGM and HAGL is equal but only the sizes of each model are different from each other.

Therewith, Bongros®-HA is provided sterile for single use.

Indications for Use

Bongros®-HA (HAGS, HAGM, HAGL) is intended for use in dental surgery.

The products may be used in surgical procedures such as:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filling of peri-implant defects in conjunction with products intended for guided bone regeneration.

Technological Characteristics and Substantial Equivalence

Bongros®-HA is substantially equivalent to predicate devices. Bongros®-HA and predicate devices are identical in intended use, indication and application. Therewith, Bongros®-HA and predicate devices are biocompatible and have similar properties.

Based on the discussion above, BioAlpha Inc. believes that Bongros®-HA is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Hyun-Seung Ryu, Ph.D
Director
BioAlpha, Incorporated
223-23 Sangdaewon-Dong, Jungwon-Gu
Seongnam, Gyeonggi-Do 462-120
KOREA

Re: K090793
Trade/Device Name: Bongros®-HA
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: March 19, 2009
Received: March 24, 2009

Dear Dr. Ryu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

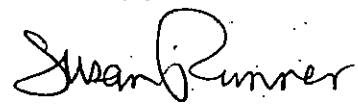
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090793

Device Name: Bongros®-HA

Indications for Use:

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090793

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)